K040592

DEC 17 2004

XIV. 510(k) Summary of Substantial Equivalence:

CLASSIFICATION NAME

Common/Usual Name: Cordis Steerable Guidewire
Proprietary Name: Cordis STEER-IT Deflecting Tip Guidewire

SPONSOR

Cordis Corporation
14201 NW 60th Avenue
Miami Lakes, Florida 33014

CLASSIFICATION

Catheter guidewires have been placed in Class II, 21 CFR 870.1330, Cathether Guide Wire.

NAME OF PREDICATE DEVICES

- Cordis Wizdom Steerable Guidewire (K953760)
- USCI PilotWire™ Deflectable Guide Wire with Commander™ Deflection Handle (K934474)
- Lake Region Manufacturing, Inc. Mandrel Guidewire (K011084)
- Lake Region Manufacturing, Inc. Steerable PTCA Guidewire (K011968)
- ACS High Torque Standard (K881787)
- Cordis ATW Marker Wire (K994358)

PERFORMANCE STANDARDS

Performance standards have not been established by the FDA under Section 514 of the Food, Drug and Cosmetic Act.

INTENDED USE OF THE DEVICE

The intended use of the Cordis STEER-IT Deflecting Tip Guidewire is the same as the Cordis Wizdom Steerable Guidewire previously cleared by FDA.

BIOCOMPATIBILITY

All materials were determined to be biocompatible.

SUMMARY STATEMENT OF SUBSTANTIAL EQUIVALENCE

The Cordis STEER-IT Deflecting Tip Guidewire is substantially equivalent to the following steerable guidewires:

- Cordis Wizdom Steerable Guidewire (K953760)
- USCI PilotWire™ Deflectable Guide Wire with Commander™ Deflection Handle (K934474)
- Lake Region Manufacturing, Inc. Mandrel Guidewire (K011084)
- Lake Region Manufacturing, Inc. Steerable PTCA Guidewire (K011968)
- ACS High Torque Standard (K881787)
- Cordis ATW Marker Wire (K994358)

They are all .014" diameter guidewires used to support the advancement of devices in the coronary and peripheral vasculature. Both the indications and contraindications are the same as previous steerable guidewires cleared by FDA.

DESIGN/MATERIALS

The Cordis STEER-IT Deflecting Tip Guidewire is similar in design and materials to the Cordis Wizdom Steerable Guidewire, Lake Region Manufacturing, Inc. Mandrel Guidewire, and the Lake Region Manufacturing, Inc. Steerable PTCA Guidewire. The difference is that the STEER-IT Deflecting Tip Guidewire employs a handle mechanism, which deflects the distal tip in two directions. The handle mechanism is butted into a stainless steel hypotube, which is soldered to a nitinol hypotube. The handle mechanism is similar to the USCI Commander™ Deflection Handle, an accessory of the USCI PilotWire™ Deflectable Guide Wire. The distal end of the STEER-IT Deflecting Tip Guidewire (3mm or 7mm) of the nitinol inner core wire is flattened, looped around and joined to the nitinol hypotube. The handle mechanism operates the movement of the distal tip by gripping the inner moveable core and allowing limited movement in two directions. (See Table 1 and Figures 1 and 2, Pages 5-7 for detailed comparison of design/material differences).

MANUFACTURING

The manufacturing processes are similar to Cordis steerable guidewires and to Lake Region guidewires cleared by FDA. Component joining methods, core grinding, coil winding, etc are the same or similar processes to predicate devices. The differences in the processes are primarily related to the handle mechanism and attachment.

SPECIFICATIONS AND TESTING

Specifications to ensure the safety and effectiveness of the device are similar to the specifications for the Cordis Wizdom Steerable Guidewire. Joint strength, torqueability, coating integrity, linear stiffness, turns to failure and dimensional testing have all been completed on the Cordis STEER-IT Deflecting Tip Guidewire. Additional testing, specific to the handle mechanism has been completed. The Cordis STEER-IT Deflecting Tip Guidewire passed all the established acceptance criteria.

CONCLUSION

This 510(k) submission represents an addition to the current Cordis steerable guidewire line. Both the Cordis STEER-IT Deflecting Tip Guidewire and the Cordis Wizdom Steerable Guidewire are .014" diameter guidewires used to support the advancement of devices in the coronary and peripheral vasculature. The Cordis STEER-IT Deflecting Tip Guidewire incorporates a handle mechanism, which deflects the distal tip in two directions to aid the clinician in positioning the guidewire. This aspect of the device is similar in function to the USCI Commander™ Deflection Handle, an accessory of the USCI PilotWire™ Deflectable Guide Wire. Biocompatibility and in vitro testing demonstrates no significant change to product characterization when compared to the predicate device. Product design and indications for use for the Cordis STEER-IT Deflecting Tip Guidewire are substantially equivalent[1] to the predicate device as cleared by FDA.

[1] A statement regarding substantial equivalence to another product is required by 21 CFR 807.87 and relates only to whether the present product can be marketed without prior reclassification or premarket approval. The present submission is therefore not related tot he coverage of any patent, and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the Commissioner of the FDA has stated, "...a determination of substantial equivalence under the federal Food Drug and Cosmetic Act relates to the fact that the product can lawfully be marketed without premarket approval or reclassification. This determination is not intended to have any bearing whatever on the resolution of patent infringement suits." 42 Fed. Reg. 45.520, et seq. (1977).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2004

Cordis Corporation
c/o Stephen M. Enos, RN
P.O. Box 025700
Miami, FL 33102

Re: K040592
Cordis STEER-IT Deflecting Tip Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: November 1, 2004
Received: November 2, 2004

Dear Mr. Enos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R Lechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040592

Device Name: Cordis STEER-IT Deflecting Tip Guidewire

Indications For Use:

The Cordis STEER-IT Deflecting Tip Guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lechner

-Off)
Cardiovascular Devices

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